# DEVELOPMENT OF A HIGH DENSITY PERCUTANEOUS CONNECTOR SYSTEM

QUARTERLY REPORT #2
July 15 - October 15, 1997

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## Abstract

This report summarizes activity over the period from July 15 through October 15 on NIH Contract N01-DC-7-2103, "Development of a High Density Percutaneous Connector System". During this period Timothy Piwonka-Corle left PI Medical and was replaced as PI on this contract by Lou Rucker. Two pedestal implants were done at HMRI with a third to follow within weeks. New fritting for the connectors using the larger pins reported last quarter was started using CABAL-12; work to be completed at IJ Research, a California company, the only company to respond to PI Medical's requests for this work. However, this is a central objective to this contract and efforts continue to find a more suitable, lower cost material.

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**THIS QPR IS BEING SENT TO YOU BEFORE IT HAS BEEN REVIEWED BY THE STAFF OF THE NEURAL PROSTHESIS PROGRAM.**

## I. Background and Review of Contract Requirements

This report summarizes activity from July 15 through October 15, 1997, on NIH Contract N01-DC-7-2103, "Development of a High Density Percutaneous Connector System". Over the course of this contract, a high density, planar, low profile connector system is being developed that incorporates pad grid array technology. This technology has unique advantages as applied to a percutaneous interconnect system. In particular the connector system will be low in profile, easy to clean, sealed against ingress of contaminants, offer low mechanical resistance to mating and demating and provide a very high number of contacts in a small diameter. The connector system will be implanted in a suitable animal model and the appropriate electrical, mechanical, and biocompatible properties of the system will be assessed. The specific technical requirements of this connector system as detailed in the contract are explained below:

- The connector will incorporate a pedestal that can be attached to the skull in a mechanically stable manner. The pedestal will be designed to accept a replaceable connector assembly. All materials of the pedestal in contact with tissue will be biocompatible and the profile of the pedestal will be low enough to minimize any physical trauma during mating and demating of the connector or due to normal physical activities.

- The connector assembly will be high-density with at least 70 contacts. The electrical isolation between the contacts or between the contacts and the body should withstand at least 18 volts without breakdown. The connector contacts when mated should be capable of passing up to 20 mA of current with less than a 1.0 volt drop across the connection. A simple method of mating and demating the upper and lower surfaces of the connector should be provided. In addition, a convenient means to attach electrical leads to the connector is needed.

- The connector will be designed from materials that are durable and can withstand the physical abuse from normal activities of daily living. The interface between the connector and the skin must be such that the passage of microorganisms into the body and fluid drainage out of the body is prevented.

- In earlier studies connectors had 5 separate loops of insulated wire, each 2 inches long. Because of wire breakage observed during these studies it is necessary to make a more durable and a more realistic part. Future connectors will have only one flat "cable" 1 to 1.5 inches long with 10 Au or Pt/Ir wires, each 1 to 10 mils in diameter, coated with Parylene and Silicone. The ends of the wires are welded so as to make 5 "loops" and the ends will be coated with Silicone. An 18 volt bias will be maintained on the connector contacts and insulated wires relative to an implanted platinum wire connected to one of the unused contacts. The leakage current of the wires will be monitored and if more than 10 nanoamperes of current is detected, the source of the leakage will be identified and corrected.

- The performance of the connector system will be tested in a suitable animal model. After six months of implantation, the connector assembly will be explanted and the

Care will be taken to have the ribbon lay flat on the skull so as not to form a pocket under the cable at the point adjacent to the connector body. This is accomplished by cutting a ramp in the pedestal so the wire exits the connector at the level of the skull. This was detailed in Figure 1 of the last report as an objective which is completed. With this method there will still be some wire movement from the animal's ear motion and rubbing against the cage and other objects. However, there should be considerably less motion and wire fatigue with this arrangement than in the earlier "looped" configurations.

## IV. Status of Fritting Experiment

PI Medical has cut a purchase order to IJ Research, Inc. of Santa Ana, CA to produce 10 "dummy" connectors using CABAL-12 glass fritting as a matrix for the pins. IJ Research is the only organization to respond to our request for this work. Dr. Rick Yoon, president, is a materials specialist. Five of the connectors will have gold pins and 5 will have Pt/Ir pins.

In discussions following the initial PO, Dr. Yoon has advised that the seal to the Ti body of the connector will be a hermetic seal. However, the seal to the proposed pins will only be a tight mechanical fit. PI Medical plans to continue the experiment with CABAL-12 and will add 5 more connectors to have Ti pins to obtain a complete hermetic seal not available with Au or Pt/Ir pins. However, we are also considering other materials including various glasses, ceramics, epoxies and Silicone polymers that would have a long implant life and other required properties. If materials other than CABAL-12 are found, especially if they are less costly and provide improved seals, an effort parallel to the CABAL-12 may be started early in the next quarter.

Since the PO and prepayment to IJ Research, the initial "dummy" step has been modified from a trial of 12 pins to the full 64 pins the connector body is capable of handling. The reason is that initial discussions were for pins with a diameter of 12 mils and the design now has pin diameters of 17 mils to improve the connection to the anisotropic elastomer between the top and bottom sections of the connector. With the increased pin size and a change from 25 mil to 30 mil center-to-center spacing, Dr. Yoon's confidence has increased so he proposed we go directly to the full 64 pin connector, skipping the 12 pin "dummy" step (although the 64 pin design is still being called a "dummy"). This uses the old connector body. The next step is to redesign a slightly larger body to accommodate 72 pins in an 8x9 matrix. This will meet the contract requirements for >70 pins.

## V. Connection of Top and Bottom Sections

The top and bottom sections of the connector will be mated with a quarter turn screw thread. This will produce sufficient force for the anisotropic elastomer requirement and will produce an acceptably low level of force on the osseointegration of the pedestal and skull and on the skull itself. This concept is in the early stage of design to be incorporated in the 72 pin connector.

## VI. Status of Implants at HMRI

Dummy connectors have been fabricated and provided to HMRI for short term implant in cats. The purpose is to evaluate skin growth to three case surfaces: plain machined surface, grooved surface and a Tantalum sponge surface. The dummy connectors have no subcutaneous cable and no leakage tests will be run, but they do have the shaped Ti bead base for osseointegration. (As of writing this report in November, two cats have been implanted and a third is scheduled for the week of November 10th.)

The entire connector will be implanted in one operation, unlike previous work in which the pedestal was allowed to osseointegrate to the skull before the connector was attached and skin growth was necessary. The one step procedure reduces the time and cost required to evaluate skin growth to the bottom portion of the connector.

## VII. Activities for the Next Contract Period

During the next quarter:

- Three short term implants will be done at HMRI for the purpose of studying skin growth and the growth will be evaluated,
- the first connectors using a CABAL-12 frit will be fabricated,
- a search for less exotic frit materials will continue in case CABAL-12 proves unsuitable,
- a method for attaching Silicone to Parylene will be developed and evaluated for use in the cable exiting the connector,
- qualification of materials as Class VI will occur as materials are clearly identified.

Several areas of development will begin to come together during the next quarter. The materials for the connector and cable will be identified and procedures for their use will be evaluated. As the materials are identified, such as the fritting, Class VI status will be verified or the Class VI qualification procedure started as the first step in eventually obtaining approval for human use. When the materials are clearly identified the design of a 72 pin connector will be finalized. This may not occur during the next quarter, but all present evaluations can be accomplished with the existing 64 pin design.